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July 10, 2008

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Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Appl. No. 10/505,137; § 371 Date: April 25, 2005

For: Solvent-Based Sterilization Of Pharmaceuticals

Inventors: BHATARAH et al.

Our Ref: 2544.1120000/RWE/SLE

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Credit Card Payment Form PTO-2038 in the amount of \$180.00 to cover the filing of an IDS under 37 C.F.R.§ 1.17(p);
- 2. Information Disclosure Statement Under 37 C.F.R. § 1.97(c);
- 3. Two (2) pages of Form PTO/SB/08A citing thirty-one (31) documents;
- 4. A copy of twenty-one (21) of the cited documents FP1-FP21;
- 5. One (1) page of Form PTO/SB/08B citing seven (7) documents;
- 6. A copy of the seven (7) cited documents NPL1-NPL7; and
- 7. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of the documents and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Commissioner for Patents July 10, 2008 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Stephanle L. Elmer Agent for Applicants Registration No. 59,244

RWE/SLE:las Enclosures

811814_1.DOC



In re application of:

BHATARAH et al.

Appl. No.: 10/505,137 (US Nat'l Phase of

PCT/GB03/00702)

§ 371 Date: April 25, 2005

For:

Solvent-Based Sterilization

Of Pharmaceuticals

Confirmation No.: 1688

Art Unit:

1617

Examiner:

Karol, Jody Lynn

Atty. Docket:

2544.1120000/RWE/SLE

Information Disclosure Statement under 37 C.F.R. § 1.97(c)

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Copies of documents FP1 to FP21 and NPL1 to NPL7 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, documents US1 to US10, cited on the attached IDS Form PTO/SB/08A are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents FP1-FP4, FP8, FP14, FP16, FP17, FP20, and FP21.

Document FP1, JP 57-32212, is in the Japanese language. An English language abstract is provided herewith as document NPL2.

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Document **FP2**, EP 0 008 454, is in the German language. U.S. Patent No. 4,263,253 is believed to be an English language equivalent of **FP2** and is cited herewith as **US3**.

Document **FP3**, JP 62-114917, is in the Japanese language. An English language abstract is provided herewith as document **NPL3**.

Document **FP4**, EP 0364 842 A1, was cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided as document **NPL8** in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

Document FP8, EP 0 525 502 B1, is in the German language. An English language abstract is provided herewith as document NPL5.

Document **FP9**, EP 0 692 491 B1, is in the German language. An English language abstract is provided herewith as document **NPL6**.

Document **FP10**, EP 0 722 344 B1, is in the German language. U.S. Patent No. 5,770,199 is believed to be an English language equivalent of **FP17** and is cited herewith as **US6**.

Document **FP16** EP 0 771 324 B1, is in the French language. U.S. Patent No. 5,834,420 is believed to be an English language equivalent of **FP14** and is cited herewith as **US7**.

Document **FP20**, DE 101 45 361 A1, is in the German language. An unverified English language translation is cited herewith as document **NPL7**.

Document **FP21**, WO 03/028736 A2, is in the German language. An English language abstract is presented on the face page of the patent.

Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038

Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Stepharlie L. Elmer Agent for Applicants Registration No. 59,244

Date:

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